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MEDICARE & CLINICAL TRIALS

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HEALTH CARE FINANCING ADMINISTRATION
The Federal Medicare Agency

Medicare offers people with Medicare the option to join some clinical trials for the diagnosis and treatment of illnesses by paying some of the patient care costs.

What is a clinical trial?

Clinical trials are one of the final stages of a long and careful research process to help patients live longer, healthier lives. They help doctors and researchers find better ways to prevent, diagnose, or treat diseases. Clinical trials test new types of medical care, like how well a new cancer drug works. The trials help doctors and researchers see if the new care works and if it is safe. They may also be used to compare different treatments for the same condition to see which treatment is better, or to test new uses for treatments already in use.

All trials are based on a set of rules called a "protocol." The protocol tells you:

- Who can or can't join the trial
- How long the trial lasts
- How often you will get tests or medications, and
- Other details of the study

Very few seniors and people with disabilities take part in clinical trials. Many people think they might lose their Medicare coverage if they do. This makes it hard to find out if new treatments work with seniors and people with disabilities. If more people take part in trials, good treatments can be approved faster, and treatments that don't work can be stopped. If you participate in a trial, you and your doctor will have more information to help decide what might be the best treatment for you.

Before you agree to participate in a trial, it will be explained to you. Then you will be asked to sign an informed consent form. This form describes the clinical trial and what is being tested. It will also explain any possible risks to you. Before you sign the form, ask questions so you understand and are comfortable with what will happen during the trial.

Why do people join a clinical trial?

People may choose to join a clinical trial to:

- Compare different treatments for the same condition to see which treatment is better.
- Test new uses for treatments already in use.
- Gain access to new treatments that are not widely available.
- Obtain medical care from doctors who lead in their field of medicine.
- Help future patients with the same illness.

Why do people choose NOT to join a clinical trial?

People may choose not to join a clinical trial because:

- They are concerned about possible risks, or
- The trial may require more visits to the doctor, or the treatment takes more time then standard care.

Medicare Payment

What costs does Medicare pay if I'm in a clinical trial?

Medicare pays for routine costs. These include costs for items and services that:

- Medicare would pay even if you weren't in a trial, like room and board for a hospital stay
- you need to get the new care, like an operation to implant an item that is being tested
- you need to treat side effects and complications of the new care

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Are there any costs that Medicare won't pay?

Yes. Medicare will not pay for:

- the new item or service that the trial is testing (except for certain devices)
- items or services provided only to collect data, and not used in your direct health care (such as monthly CT scans for a condition that usually requires one scan)
- items and services the trial gives you or any enrollee for no charge
- coinsurance and deductibles.

I'm in a clinical trial now. Are the routine costs of my trial covered by Medicare?

Check with the doctor or trial coordinator to see if the trial meets the following requirements for Medicare coverage.

The routine costs of services given on or after September 19, 2000 are covered by Medicare if the trial is:

· funded by, or the center or cooperative group conducting the trial is funded by:

- National Institutes of Health (NIH),
- Centers for Disease Control and Prevention (CDC),
- Agency for Healthcare Research and Quality (AHRQ),
- Health Care Financing Administration (HCFA),
- Department of Defense (DoD), or
- Department of Veteran's Affairs (VA),

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AND

· The trial should also be under an "investigational new drug" application (IND) reviewed by the FDA, or is exempt from having an IND. (Once criteria is developed and the certification process is in place, exempt trials must qualify to continue Medicare coverage.)

AND

· The trial evaluates an item or service that falls within a Medicare benefit category. The item or service must not be statutorily excluded from coverage. For instance, trials of most prevention activities are excluded.

AND

· The trial is designed to treat or diagnose a disease. Also, you must be diagnosed with the disease the trial is about, unless you are part of the control group in a diagnostic trial.

Other trials can ask Medicare to pay their Medicare patients' costs. If your trial isn't described above, or if you're not sure whether your trial meets all the requirements, ask your doctor or the trial coordinator if Medicare covers its routine costs.

Other Insurance

I'm in a Medicare + Choice Plan. Can I still be in a clinical trial?

Yes. If you are in a Medicare + Choice Plan, you will get the same coverage for clinical trials as a person in the Original Medicare Plan. This means that your Medicare managed care plan cannot keep you from joining a clinical trial. However, you should tell your plan before you start a clinical trial. That way, the plan can still keep track of your health care services.

In addition, because you have the same coverage as a person in Original Medicare, you will have to pay the Original Medicare Plan coinsurance for the clinical trial services. However, you will not be responsible for the Part A or Part B deductible.

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Will my employer group plan cover the routine costs in a clinical trial?

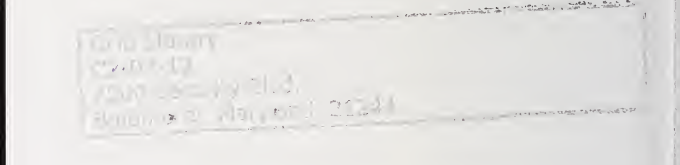
Whether your employer plan covers all or some of the costs of these services depends on:

- the terms of the employer plan, and
- whether the employer plan or Medicare pays your bills first (is the primary payer).

Before you join a trial, check with your employer group plan or the benefits manager of the employer to find out what benefits are covered. Call 1-800-MEDICARE (1-800-633-4227) for a Medicare booklet on who pays first.

Will my supplemental (Medigap) plan pay for my coinsurance and deductibles if I am in a clinical trial?

If the routine costs of your trial are covered by Medicare, then your Medigap policy must pay coinsurance amounts for those costs. If your Medigap policy also covers deductibles and excess charges, it must also pay these amounts for routine services.



More Information

I want to find out more about clinical trials that might help me. What can I do?

• Talk to your doctor.

• Look on the Internet at www.clinicaltrials.gov. This site lists government and private studies across the country. It also has more information to help you understand clinical trials. This site is a service of the National Library of Medicine. If you do not have a personal computer, your local library or senior center may be able to help you find this information.

To find out about cancer trials:

• Call 1-800-4-CANCER (1-800-422-6237 or TTY: 1-800-332-8615 or the hearing and speech impaired) for information. This toll-free Cancer Information Service provides cancer information and help locating cancer clinical trials. This is a service of the National Cancer Institute.

• Look on the Internet at http://cancertrials.nci.nih.gov. This site lists trials for patients with cancer, and detailed information about cancer clinical trials. This site is a service of the National Cancer Institute. If you do not have a personal computer, your local library or senior center may be able to help you find this information.

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